

REMARKS/ARGUMENTS

The above amendments and following remarks are submitted to supplement those filed with the response and RCE filed on February 14, 2008. This supplemental amendment is submitted following the interview of April 10, 2008 with Examiner Devi and attended by Dr. Jan Poolman (present as an expert in the field of vaccines, particularly meningitis vaccines, and an employee of the licensee of this application) and Mr. Michael Lubienski (a European attorney and representative of the licensee) and the undersigned.

I. Claims

Claims 25, 30-36, 39-42, 44-46, 50, 52 and 55-58 are pending. Claims 50 and 55 are amended. Claims 56-58 are newly presented. All claim language is supported in the application and in the priority document. No new matter is introduced into the specification by these amendments.

Claims 50 and 55 are amended by this paper to introduce language that was suggested by the examiner. This language is supported in the specification at page 20 lines 24 et seq and in Example 8.

Claim 55 is also amended to introduce the lower limit of the epitope as being at least 8 amino acids. Support for the use of the term “epitope” and/or “fragment” of the OMP85 sequence as used in claim 55, and for the polypeptide to have the ability to induce antibodies which interfere with adherence of *N. gonorrhoeae* in the gonococcal adherence assay is found at page 20, line 25 to page 21, line 4 and in Example 8. The support for the size limitation as minimally at least 8 amino acids of the OMP85 sequence to just short of the full sequence is found in the same passage. Further, the examples, particularly Example 8, provides a description of polypeptide containing an epitope of OMP85 within the first 178 amino acids of the N-terminal sequence of SEQ ID NO: 2. Note that SEQ ID NO: 2 is 95% identical to SEQ ID NO: 4, and these fragments from both sequences are greater than 95% identical.

New claim 56 is a new independent claim added to submit for consideration the concept of identity greater than 90%. Support for this percentage is provided at page 19, lines 26-27 and in the OMP85 proteins identified in other *Neisserial* species in Figs. 3, 4 and 7A and 7B

New claims 57 and 58 are supported in the original specification at page 19, lines 2-10.

As discussed at the above-noted interview, the inventors discovered that this particular OMP, i.e., OMP85 of SEQ ID NO: 4 or 2, or fragments of this OMP85, could induce antibodies capable of interfering with binding between the cellular target and the bacteria in the above-noted cell adherence assay. This discovery allowed the inventors to determine that the OMP85 and/or fragments thereof would be useful in an immunogenic composition. This hurdle was not an inconsiderable one, given the history of meningitis vaccine research over the years. That fragments within the larger OMP85 protein would have the same function is clearly an aspect of the invention contemplated and disclosed by the inventors. See the cited portions of the specification above. Thus, the inventors provided the identification of the key useful protein itself, disclosure that epitopic fragments within the larger sequence having the same biological function would be useful for the same purposes, disclosure of one specific fragment in the examples, and an assay to determine relevant biological activity of such fragments. It is within the inventors' contribution to the art that a fragment within the OMP85 SEQ ID NO: 4 sequence that evidences such activity may form part of an immunogenic composition. Such contribution should be recognized as falling within the scope and breadth of the inventors' claims.